NELAC REGULATORY COORDINATION COMMITTEE
TELECONFERENCE – FEBRUARY 23, 2000

1. The meeting was called to order by Chair, Dr, Michael Miller at 12:30 PM EST. The agenda and supporting materials had been distributed previously to the Committee members by electronic mail.

The following members participated in this teleconference:

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| Dr. Michael Miller, Chair | Dr. Carl Kircher |
| Susan Smith | Ilona Taunton |

Randy Querry (proposed replacement for Roxanne Robinson, who has resigned)
Dr. Marcia Davies (guest, Chair, Program Policy & Structure standing committee)

A quorum of voting members was not present for this teleconference, so the minutes for the Committee's business from the NELAC Interim Meeting could not be approved.

2. Dr. Miller related that the revised application form consistent with NELAC Chapter 4 requirements has been posted on the NELAC internet site. Still, any Committee member comments on this form are welcome.

3. Dr. Miller has received laboratory accreditation regulations and legislation from 5 states thus far. Final Committee action on these (and others to be received later) has yet to be determined. One option might be to review these documents and to forward any questions, comments, or potential concerns to the relevant NELAP-recognized accrediting authority. Another option could be to evaluate these regulations for posting on the NELAC internet site. This topic will be addressed at the next teleconference.

4. The remainder of the teleconference continued the discussions on the Scope of Accreditation offered by NELAP through the NELAC-defined Fields of Testing concept and on the considerations for restructuring the current combination that is based on Regulatory Program – Test Method – Analyte. Dr. Kircher related that this issue is being considered, at least indirectly, by several NELAC standing committees, by the eleven recognized NELAP accrediting authorities, and by the Environmental Laboratory Advisory Board, who has formed a Workgroup to study this issue, evaluate various options, and present its recommendations.

At the previous meeting, George Avery presented draft language to NELAC Chapters 1, 2, & 4 that would be consistent with expressing NELAP Fields of Testing as combinations of Sample Matrix – Test Method.

Dr. Davies pointed out, as part of the problem, that the term "Fields of Testing" is often confused with and interchanged with the term "Scope of Accreditation." All participants agreed that we are more accurately considering Scope of Accreditation while dealing with this issue; indeed the ELAB Workgroup may recommend a terminology change in the NELAC Glossary to reflect this usage.

Dr. Davies also related that, during NELAC VI next June, there will a joint session between the Program Policy and Structure Committee and the Regulatory Coordination Committee to consider the best options for Scope of Accreditation. The deliberations will continue in the Regulatory Coordination Committee meeting, to be held after the joint session. All committee members believed this arrangement to be an excellent idea for discussing this important issue.

*** Omission of "Analyte" from the Scope of Accreditation ***

Ms. Taunton believed that accredited laboratories would prefer the NELAP Scope to be Program – Method combinations. The inclusion of "Analyte" into the combinations would (and currently) result in far too much confusion in working with reciprocity.

Dr. Davies said that laboratory validation for specific analytes is really a data user issue. It should be the client's or EPA's responsibility to verify competent laboratory performance for analytes reported under a particular test method.

This should also be the data user's responsibility, even if the NELAP on-site laboratory assessment covered analytes for a test method that were different than the analytes reported in test results. Ms. Taunton agreed that even if "Analyte" is still included in the scope of laboratory accreditation, NELAC cannot guarantee laboratory testing performance for these analytes 100% of the time.

For laboratories accredited in Germany under A2LA, the scope of accreditation under Germany's system does go down to detail at the analyte level. However, if the laboratory is not A2LA-accredited, then the scope only is delineated at the "method" level.

*** "Methodology" versus "Method" Considerations ***

One commenter felt it was too unnerving to switch from "method" to "methodology" as the basis for accreditation. "Method" should be kept as a more realistic alternative. When asked about further detail, this person also believed it was a good idea to keep equivalent method citations separate as well. Laboratories would probably like to group equivalent methods together (e.g. EPA 325.3, SM4500Cl- C, ASTM D512-89A, USGS I-1184-85, and AOAC 973.51) since NELAC Standards govern laboratory performance for all of them. However, as a compromise to the public and to environmental regulatory officials, the method citations should be listed separately so that there is no confusion as to which test methods really are equivalent.

*** "(Environmental) Program" versus "(Sample) Matrix" Considerations ***

Dr. Davies said that converting the Scope of Accreditation from "Program" to "Matrix" is doable under NELAC since the Glossary defines what the sample matrices are. The issue of which term is "right" or "wrong" is irrelevant. As for changing the list of matrices in the Glossary if "Matrix" is adopted into the Scope of Accreditation, Dr. Davies related that the choice of matrices listed may be driven more by regulatory and client user requirements than by scientific analytical capability. For example, soils and biological tissues may be digested, extracted, and analyzed in the same procedural manner, but the regulatory treatment of the test results may be far different.

*** Criteria & Procedures for Changing the NELAP Scope of Accreditation ***

After considerable discussion, the participants agreed that the minimum criteria to consider in selecting the basis for NELAP's Scope of Accreditation are:

- data user needs
- can the recognized state NELAP authorities implement the resulting accreditation system
- cost-effective laboratory activities and operations

As to the appropriate forum for deciding the structure and basis of the Scope of Accreditation, the participants agreed that NELAC as a Conference should make the decision and vote it in as part of the Standards.

*** Regulatory Issues? ***

If the Scope of Accreditation is changed from the current combination of Program – Method – Analyte, the consensus answer to the question of whether regulatory modifications would be needed is a "definite Maybe." NELAC is a standard-setting organization, but when regulatory concerns are factored in, the Scope of Accreditation issue could potentially become really complex. For example, when EPA regulations refer to laboratory approval under the Safe Drinking Water Act, does the approval apply globally to the drinking water program or does the approval pertain to analytes within this program? If a Quality Assurance Project Plan approved under RCRA specifies testing to be done by a certified laboratory, does the certification refer globally to the entire laboratory as an organization, or does the laboratory have to be certified for individual analytes to be monitored under the approved Project Plan? The answers to these questions could be different based on different stakeholders' interpretations of these issues.

5. As the allotted time for this teleconference was used up, this meeting adjourned at 2:00 PM EST. The next next scheduled teleconference for this Committee is scheduled for April 12.

ACTION ITEMS
REGULATORY COORDINATION COMMITTEE MEETING
FEBRUARY 23, 2000

1. Recommend to the NELAC Board of Directors that EPA and the NELAC Quality Systems Committee evaluate the impact of the EPA QA/G-7 document (Guidance on Technical Audits and Related Assessments for Environmental Data Operations) on NELAP laboratories and states (Action by 4/30/00)

2. Review laboratory accreditation application posted in the NELAC internet site (Action by 5/31/00)

3. Consider development of model generic SOP's and Quality Manuals for small laboratories (Ongoing)

4. Consider proposal for restructuring the NELAP Scope of Accreditation (Ongoing)

5. Review the semiannual EPA regulatory agendas for October 1999 and April 2000 (Action by 7/1/00)

6. Collect and evaluate recent state regulations and legislation for the implementation of NELAC (Action by 7/1/00)